K070212

510(k) Summary
CiTop™ 0.014" Guidewire

Date: August 29, 2007

Submitter Information:

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OCT 12 2007

Contact Person:

Naáma Oren
Director of QA and Regulatory Affairs

Device Identification

Trade Name:	CiTop™ 0.014" Guidewire
Device Common Name	Catheter Guide Wire
Classification Name:	Catheter Guide Wire
Classification:	Class II (74 DQX/21CFR 870.1330)

Predicate devices:

The CiTop™ 0.014" Guidewire is substantially equivalent to the following predicate devices:

- Asahi PTCA & PTA guidewire Confianza Pro – cleared under K041531
- Cordis STEER-IT Guidewire - cleared under K040592;
- LuMend Frontrunner CTO Catheter and Accessories – K013284

Device Description:

The CiTop™ Guidewire has an outside diameter of 0.014" (0.36 mm) and a length of 280 cm.

The CiTop™ 0.014" Guidewire can be torqued to facilitate navigation through the vasculature. A handle control is supplied with the guidewire to facilitate torque and tip shaping for deployment and positioning according to standard practices. The distal tip can be momentarily shaped into an arched formation by the operator to aid in releasing a wedged guidewire and allow its advancement through difficult occlusions. A platinum marker coil at the distal tip aids visualization under fluoroscopy.

The CiTop™ Guidewire is supported by a stainless steel helical cut accessory shaft with an outside diameter of 0.023" and length of 126cm. The support accessory may be independently torqued and its distal end shaped. The support accessory operates

as an aid in the advancement of the CiTop™ Guidewire and as an adjustment to the flexibility of the distal end of the CiTop™ Guidewire .
The CiTop™ 0.014" Guidewire is supplied in a protective dispenser, that is packaged in a single-use sterilizeable pouch. The Pouch is labeled, and placed in an individual protective carton for sterilization.
The CiTop™ 0.014" Guidewire is a single use/disposable product with a nitinol shaped tip. The Guidewire is used to gain intravascular access to and facilitate the positioning and exchange of interventional devices in small-diameter, tortuous vasculature.

Intended Use

The CiTop™ Guidewire is intended for use in angiographic procedures to facilitate the intra-luminal placement of the wire beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Technological Characteristics

The components of the CiTop™ 0.014" Guidewire are similar in basic materials, design, construction and performance to the predicate devices. The distal tip has been designed to improve performance characteristics in passing total occlusions (i.e. tip flexibility, tip shaping and shape retention / relaxation).

Safety and Performance Testing

Biocompatibility of the CiTop™ 0.014" Guidewire materials has been verified in accordance with ISO 10993-1. Biological evaluation of Medical Devices – Part 1. Materials test results confirmed biocompatibility of the subject device when tested as an external communicating, blood contact, short duration (<24 hours) device.

Design analysis, in vitro and in vivo data confirm the safety and effectiveness of the device and that the basic functional characteristics are substantially equivalent to the predicate devices cited. Device evaluation based on testing specified in the FDA's Coronary and Cerebrovascular Guidewire Guidance Document (January 1995) and included in vitro tensile, torque strength, torqueability, tip flexibility, biocompatibility and catheter compatibility tests. All data was within device specification requirements, as well as standard requirements and predicate performance expectations. Subject product testing has yielded acceptable safety & performance outcomes.
In addition, verification performance testing also yielded acceptable results. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate that the CiTop™ 0.014" Guidewire is substantially equivalent to the cited predicate devices.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, the subject CiTop™ 0.014" Guidewire meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available guidewires/cited predicates.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2007

Ovalum, Ltd.
c/o Mr. Jonathan Kahan
Hogan & Hartson, LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K070212
Trade/Device Name: CiTop Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: August 31, 2007
Received: August 31, 2007

Dear Mr. Kahan:

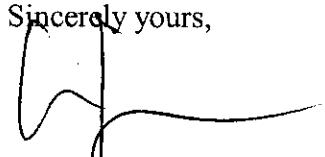
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070212

Device Name: CiTop™ 0.014" Guidewire

Indications for Use: The CiTop™ Guidewire is intended for use in angiographic procedures to facilitate the intra-luminal placement of the wire beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Prescription Use ___X___ (Per 21 CFR 801.109 subpart D) OR Over the Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular De
510(k) Number K070212